UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE MYOVANT SCIENCES LTD. SECTION 16(b) LITIGATION	Lead Case No. 20-cv-1807 (JGK)
This Document Relates To: ALL ACTIONS.	(Consolidated with No. 20-cv-2542 (JGK))

MEMORANDUM OF LAW IN SUPPORT OF THE MOTION OF ROIVANT SCIENCES LTD. TO DISMISS THE THIRD AMENDED COMPLAINT

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MISCELLANEOUS

The Court dismissed Plaintiffs' Second Amended Complaint because Plaintiffs had not plausibly pleaded that Roivant had profited from its transactions in Myovant stock, an essential element of any claim under Section 16(b) of the Securities Exchange Act of 1934. 15 U.S.C. § 78p(b). As the Court noted, the market price for Myovant stock was $7.51 when the Memorandum of Understanding was signed and $5.46 when the Transaction Agreement was signed. Opinion & Order (Dkt. 42) ("Opinion") at 13. Those prices were "significantly below" the lowest price at which Roivant purchased Myovant stock. *Id.* The Court then concluded:

> The plaintiffs allege that the true sale price for Roivant's holdings of Myovant stock must have been significantly higher due to (1) the control premium that Sumitomo achieved in the transaction and (2) *the positive clinical trial result for one of Myovant's drugs that Roivant must have shared with Sumitomo*. This second allegation, made without any factual support in the SAC, is *rendered even less plausible by the fact that Myovant (let alone Roivant, a distinct corporate entity) did not know the results of the trial until after the Transaction Agreement was executed*. The plaintiffs are thus basing their theory of profit on *unsupported speculation* that either Sumitomo signed a binding agreement to pay a significant premium for an asset based on information it would not have until several weeks later or *that Myovant correctly predicted the clinical trial results, then shared this prediction with Roivant, who then shared it with Sumitomo*. Such elaborate machination is possible, but "without some further factual enhancement it stops short of the line between possibility and plausibility of 'entitle[ment] to relief.'"

Id. at 14 (emphasis added) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). The Court accordingly dismissed the complaint. *Id.* at 15.

Plaintiffs' Third Amended Complaint differs from their prior complaint in two principal ways. *First*, Plaintiffs have changed their theory. Now they are alleging that Roivant itself

conducted the clinical trial, learned the results throughout the course of the trial, shared the results with Sumitomo, and did so before the Memorandum of Understanding was signed on September 6, 2019. *E.g.*, Third Am. Compl. ("TAC") (Dkt. 43) ¶¶ 52, 55, 65-69, 79. That timing is critical because the Memorandum of Understanding set the amount that Sumitomo would pay Roivant, and that amount did not change. *E.g., id.* ¶¶ 23, 25.

Second, Plaintiffs now cite to publicly available documents—chiefly the Clinical Trial Protocol for the trial and an article about the trial published in the *New England Journal of Medicine*—in an effort to provide the "factual enhancement" that was lacking in their prior complaint. Opinion at 14 (quoting *Twombly*, 550 U.S. at 557). But those documents have the opposite effect; they contradict and disprove Plaintiffs' theory. The truth is, as the Court previously recognized, "Myovant (let alone Roivant, a distinct corporate entity) did not know the results of the trial until after the Transaction Agreement was executed." Opinion at 14. The Clinical Study Protocol and journal article confirm this timeline. And Plaintiffs' own allegations separately demonstrate that Roivant in particular did not know the information.

The Court should dismiss the TAC with prejudice.

BACKGROUND

A. Roivant, Myovant, and Relugolix

Roivant Sciences Ltd. ("Roivant") is a private biopharmaceutical company that founds, seeds, and incubates subsidiary companies, called "Vants," that focus on particular health issues or biopharmaceutical products. TAC ¶ 14. Prior to the Sumitomo transaction at the center of this case, one of Roivant's subsidiaries was Myovant Sciences Ltd. (together with its subsidiaries, "Myovant"), which had developed two different pharmaceutical products, the more prominent of which was relugolix. *Id.* ¶¶ 60-61.

Relugolix is an oral medication that is in development for the treatment of uterine fibroids and endometriosis. TAC ¶ 60; Evaluate Vantage Article (TAC Ex. F) at 2. At the time that the Sumitomo transaction was being negotiated and signed, relugolix was also being tested as a treatment for prostate cancer. TAC ¶ 64; Neal D. Shore et al., *Oral Relugolix for Androgen-Deprivation Therapy in Advanced Prostate Cancer*, 382(23) N. Engl. J. Med. 2187 (2020) ("Shore Article") (TAC Ex. J) at 2188. Specifically, the drug was the subject of a Phase III clinical trial to determine its safety and efficacy in comparison to an injectable prostate cancer drug called leuprolide. TAC ¶¶ 64, 75.

Myovant sponsored the clinical trial. *Id.* ¶ 65. The National Institutes of Health ("NIH") lists Myovant as the "Responsible Party" for the trial, and further confirms that the investigators for the trial were affiliated with Myovant. *See* NIH Summary of Clinical Trial ("NIH Summary") (TAC Ex. G) at 10-11. Myovant submitted a lengthy Clinical Trial Protocol to the Food and Drug Administration ("FDA") that does not indicate any involvement in the trial by Roivant. Clinical Trial Protocol (Williams Decl. Ex. 1).[1] Indeed, neither document so much as uses the word "Roivant."

Myovant began enrolling patients in the clinical trial in April 2017, but did not enroll sufficient patients until October 2018. TAC ¶ 76. By then, Myovant had enrolled a total of 930

[1] Exhibit I to the TAC is an excerpt from the Clinical Trial Protocol, which is publicly available as a supplement to the Shore Article at the URL cited by Plaintiffs at TAC ¶ 72, Figure 2. The complete Clinical Trial Protocol is attached as Exhibit 1 to the Declaration of John Williams submitted in support of this motion. It is OCR'd to allow for easier searching by the Court, and all page numbers referenced are the page numbers for the pdf of the exhibit.

patients in the trial, randomly assigning 622 to receive relugolix treatment and 308 to receive leuprolide treatment. *Id.* ¶ 74. Patients were treated with either drug for the course of 48 weeks, and then each patient made a "safety follow-up" visit 30 days after treatment ended. *Id.* ¶ 73. The Clinical Trial Protocol described in detail how Myovant would evaluate the efficacy of relugolix. The "primary clinical outcome to be measured" in the study, or the "primary endpoint," was "sustained testosterone suppression . . . through 48 weeks." *Id.* ¶ 71. The protocol also provided for the analysis of several "secondary endpoints" that bore on the safety and efficacy of relugolix, like patients' testosterone levels on particular days of the study (e.g., day 4, or day 15). *Id.*

Because relugolix and leuprolide are administered in different ways, the assignment of patients to the relugolix and leuprolide groups was not blind in the sense that the physician and the patient each knew which drug the patient had received. *Id.* ¶ 75. But the endpoints for the study required precise measurements of patients' testosterone levels (or other chemicals in the patients' fluids, like "follicle-stimulating hormone"), so clinical trial investigators sent periodic samples from these patients to a centralized laboratory for analysis. NIH Summary (TAC Ex. G) at 4-7; Shore Article (TAC Ex. J) at 2188; Clinical Trial Protocol (Williams Decl. Ex. 1) at 168-69. Unlike the patients and physicians, *the centralized laboratory was blinded*, meaning that the samples sent to the laboratory and the results the laboratory processed did not indicate whether a patient had received relugolix or leuprolide. Shore Article (TAC Ex. J) at 2188. The last patient's data for analyzing the primary endpoint was collected on October 25, 2019. NIH Summary (TAC Ex. G) at 3; *see* NIH, *Protocol Reg. Data Element Definitions for Interventional & Observational Studies* (Oct. 1, 2020), *available at* https://prsinfo.clinicaltrials.gov/definitions.html (NIH definition of "Primary Completion Date").

The Clinical Trial Protocol also describes when Myovant would analyze the endpoints with the data collected over the course of the study. The protocol explains that there were "two analyses for the study, a primary analysis and a final analysis." Clinical Trial Protocol (Williams Decl. Ex. 1) at 121. "The primary analysis of efficacy and safety will occur after approximately the first 915 patients have been randomized to the study . . . and have had the opportunity to be evaluated for 48 weeks and complete the 30-day safety follow-up visit." *Id.* After those 915 patients were enrolled, Myovant would continue to enroll patients with "metastatic" prostate cancer until 390 metastatic patients had been enrolled, and then Myovant would conduct the "final analysis" after those additional patients had completed their 48 weeks of treatment and 30 days of follow-up. *Id.* at 121, 154.

The "primary analysis" was the first time that Myovant would review data relating to the potential efficacy of relugolix; there was no "interim efficacy analysis" that took place during the course of the study. *Id.* at 186. The Clinical Trial Protocol shows that the primary analysis did not take place until November 2019, after the MOU was signed in early September 2019.

That timing is necessitated by the study's enrollment. Myovant could not begin the primary analysis before 915 patients had completed 48 weeks of treatment and their 30-day safety follow-up visits. *Id.* at 121. Because only 930 patients had been enrolled in the trial by October 2018, TAC ¶¶ 74-76, it goes to reason that 915 patients would not have completed their approximately year-long course of treatment until October 2019.

Moreover, Myovant told the FDA in the Clinical Trial Protocol that it would conduct its efficacy analysis through a "statistical analysis plan [that] will be prepared and finalized before database lock for the primary analysis." Clinical Trial Protocol (Williams Decl. Ex. 1) at 121. The first statistical analysis plan was approved by Myovant on September 12, 2019, and was expressly prospective: It states that its "purpose . . . is to describe the analyses *planned* for phase

3 study MVT-601-3201 (HERO)." *Id.* at 321, 327 (emphasis added). After the FDA provided feedback on this first version of the statistical analysis plan, Myovant refined the document and approved a final version on November 7, 2019. *Id.* at 379, 436.

After completing its efficacy analysis pursuant to this plan, Myovant released the results of the clinical trial to the public on November 19, 2019. TAC ¶ 54. These results indicated that relugolix was effective in treating prostate cancer. *Id.* ¶¶ 81-85.

B. The Sumitomo Transaction

While the relugolix trial was proceeding, Roivant and Sumitomo Dainippon Pharma Co. Ltd. ("Sumitomo") signed a non-binding Memorandum of Understanding ("MOU") on September 6, 2019. *Id.* ¶ 17. The two companies agreed in principle that Roivant would sell Sumitomo a collection of assets, and Sumitomo would pay Roivant $3 billion in cash. MOU (TAC Ex. A) §§ 1, 3. In particular, Roivant agreed to sell: (1) Roivant's interest in five affiliated "Vants," along with options to acquire Roivant's interest in six others; (2) a large equity stake in Roivant; (3) rights to two of Roivant's technology platforms; and (4) Roivant's agreement to transfer certain key employees. TAC ¶¶ 17-22; MOU (TAC Ex. A) §§ 1-3.

As to the five "Vants," Roivant agreed to sell three privately held companies: Enzyvant, Altavant, and a third "vant" to be named later. MOU (TAC Ex. A) § 1(i)(3)-(5). The two others—Myovant and Urovant—were publicly traded. *Id.* § 1(i)(1)-(2). At the time it entered into the MOU, Roivant owned approximately 75% of Urovant, and 40,765,599 shares, or about 45%, of Myovant. *Id.* Included in that total were 2,424,242 common shares of Myovant that Roivant had purchased in June 2019. Compl. ¶ 20(a) (Dkt. 1), *Chechele v. Roivant Sciences Ltd.*, No. 20-cv-2542 (consolidated with this action).

On October 31, 2019, Roivant and Sumitomo formalized the transactions contemplated by the MOU in a binding Transaction Agreement. TAC ¶ 25; Transaction Agreement (TAC Ex.

B). The general deal details had not changed: Sumitomo agreed to pay Roivant $3 billion in cash for the set of assets contemplated by the MOU. TAC ¶ 23; *Compare* MOU (TAC Ex. A) §§ 1-3 *with* Transaction Agreement (TAC Ex. B) Recitals. The Transaction Agreement allocated $1 billion of Sumitomo's payment to the equity in Roivant itself, but did not allocate the remaining $2 billion between the other assets—Roivant's interests in its affiliates, options to purchase further affiliates, technology platforms, and several key employees. TAC ¶¶ 17-22, 28; Transaction Agreement (TAC Ex. B) Recitals, §§ 2.01-03, 7.13(b).

Although not central to this motion, Plaintiffs implausibly allege that the $2 billion was paid only for Roivant's interest in the five Vants. Plaintiffs claim Roivant gave Sumitomo all of the other assets for free—*two* technology platforms, options to buy *six* companies, and employment rights to several key employees—as "deal sweeteners." TAC ¶¶ 27-32. They rely on a part of the Sumitomo Disclosure Schedule to the Transaction Agreement, which uses the short-hand term "Company Equity" for the $2 billion in consideration not allocated to the purchase of the Roivant equity. *Id.* ¶¶ 27-28; Sumitomo Disclosure Schedule (TAC Ex. C) at 3. But that schedule refers to Section 2.03 of the Transaction Agreement, which states that the schedule allocates the total consideration paid by Sumitomo between the equity Sumitomo purchased in Roivant itself, on the one hand, and "the Company Equity *and the other assets purchase[d] by Sumitomo*, on the other hand." Transaction Agreement (TAC Ex. B) § 2.03 (emphasis added); TAC ¶ 26. The Sumitomo Disclosure Schedule further makes clear that it is "qualified in its entirety by reference to the specific provisions of the [Transaction] Agreement and is not intended to constitute . . . agreements of Sumitomo, except as and to the extent provided in the Agreement." Sumitomo Disclosure Schedule (TAC Ex. C) at 2.

Roivant and Sumitomo also agreed that Roivant would acquire and deliver additional Myovant shares (the "Top-Up Shares"), over and above the Transaction Agreement Shares, so

that Sumitomo would hold at least 50% of Myovant's stock at closing. TAC ¶ 34. The day the Transaction Agreement was signed, Myovant disclosed to the market that its Board of Directors had approved the transaction. Myovant 8-K (Williams Decl. Ex. 2). Myovant further disclosed that Roivant would be purchasing the Top-Up Shares "at prices not below market trading prices and delivering such shares, or voting rights with respect thereto, to" Sumitomo. *Id.*

On the day that Roivant and Sumitomo announced the Transaction Agreement, Myovant stock closed at $5.46 per share. TAC ¶ 50. About three weeks later, on November 19, Myovant announced the successful results for the relugolix clinical trial. *Id.* ¶ 54. Myovant's stock price jumped from $6.06 per share to $12.92 per share in one day, and subsequently climbed to more than $19 per share. *Id.*

Roivant had not purchased any of the Top-Up Shares by the date of the public disclosure of the clinical trial results. *See id.* ¶¶ 38-39. Between November 20 and December 17, Roivant purchased the 4,243,005 Top-Up Shares at prices ranging from $11.80 to $18.85. *Id.* ¶ 39. The Roivant-Sumitomo transaction closed on December 27, 2019. *Id.* ¶ 95.

C. Procedural History

Plaintiffs, who allege they are Myovant shareholders, wrote to Myovant demanding that the company bring a Section 16(b) (§ 78p(b)) action against Roivant within a week of the deal closing. *Id.* ¶ 12. On February 28, 2020, despite a clear incentive to recover any actual profit earned by Roivant, Myovant responded that its Board had decided to not pursue such an action. *Id.* Notwithstanding Myovant's conclusion that an action was unwarranted, Plaintiffs Donoghue and Rubenstein filed a complaint the next day, and Plaintiff Chechele filed a separate complaint soon thereafter. *See* Complaint, *Donoghue v. Myovant Sciences Ltd.*, No. 20-cv-1807 (Dkt. 1); Complaint, *Chechele v. Roivant Sciences Ltd.*, No. 20-cv-2542 (Dkt. 1).

After the cases were consolidated into the present action, Plaintiffs filed a first Amended Complaint on May 5. Dkt. 27. Roivant moved to dismiss that complaint in on June 19. Dkt. 34. Plaintiffs chose to amend their complaint again rather than oppose Roivant's Motion. The Second Amended Complaint ("SAC"), filed July 10, introduced Plaintiffs' central contention—Roivant "must have" given Sumitomo a "sneak peek" at the positive results of Myovant's relugolix trial. SAC (Dkt. 36) ¶¶ 44-45.

Roivant filed a Motion to Dismiss that raised three principal arguments: (i) that Plaintiffs had failed to match a purchase and sale of stock, (ii) that Plaintiffs had not pleaded Article III standing for Myovant, and (iii) that Plaintiffs' theory of profit was implausible. Dkt. 38. Although the Court disagreed with Roivant's first two arguments, it agreed with the third and dismissed the SAC.

"On its face," the Court reasoned, the transaction in which Roivant sold its Myovant stock to Sumitomo and purchased other Myovant stock "did not result in a profit." Opinion at 13-14. Plaintiffs lacked allegations sufficient to overcome the fact that the "prevailing market prices of Myovant stock at the time of both the MOU and the execution of the Transaction Agreement ($7.51 and $5.46, respectively) was significantly below the prices that Roivant paid for the Top-Up Shares ($11.80 and above)." *Id.* at 13. The Court rejected Plaintiffs' sneak-peek theory as "unsupported speculation [that] does not amount to a reasonable foundation." *Id.* at 15. As the Court explained, Plaintiffs' theory rested on the "elaborate machination" that "Myovant correctly predicted the clinical trial results, then shared this prediction with Roivant, who then shared it with Sumitomo." *Id.* at 14.

Plaintiffs filed their Third Amended Complaint (Dkt. 43) on February 10, 2021. In it, they seek to bolster their sneak-peek theory through a description of the relugolix clinical trial based on the Shore Article and the Clinical Trial Protocol. Plaintiffs allege Roivant not only had

access to the clinical trial data before it was publicly announced, but that Roivant had access to the data before Myovant (a distinct corporate entity) had even finished conducting the trial. *See, e.g.*, TAC ¶¶ 85, 87-91. Further, they hypothesize, Roivant then shared that data with Sumitomo before the MOU was signed in early September. *Id.* ¶¶ 52-55. Thus, they claim, the $3 billion agreed to at that time already incorporated the clinical data. *Id.* ¶¶ 51-52.

The Shore Article and the Clinical Trial Protocol contradict Plaintiffs' sneak-peek theory. They show that no one had access to the results of the study until after the Transaction Agreement was signed. Worse yet, the Shore Article and Plaintiffs' own allegations render implausible Plaintiffs' specific contention that *Roivant* knew the results of the study earlier than November 2019. Plaintiffs' theory still fails.

LEGAL STANDARDS

In deciding motions under Rules 12(b)(6) and 12(b)(1), a court accepts the material facts alleged in the complaint as true, draws all reasonable inferences in plaintiffs' favor, and decides whether plaintiffs have adequately and plausibly pleaded a valid claim for relief. *E.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009); *Twombly*, 550 U.S. at 555-56. The critical inquiry is whether a pleading contains "*nonconclusory* factual content raising a *plausible* inference of misconduct." *Pension Benefit Guar. Corp. ex rel. St. Vincent Catholic Med. Ctrs. Ret. Plan v. Morgan Stanley Inv. Mgmt. Inc.*, 712 F.3d 705, 718 (2d Cir. 2013) (emphasis in original); *see Iqbal*, 556 U.S. at 678. A plaintiff's desired inference is not plausible if another inference is the "obvious alternative explanation" from the facts alleged. *Iqbal*, 556 U.S. at 682 (quoting *Twombly*, 550 U.S. at 567).

In conducting this analysis, the court may consider both the allegations in the complaint and "documents that are referenced in the complaint, documents that the plaintiff relied on in bringing suit and that are either in the plaintiff's possession or that the plaintiff knew of when bringing suit, or matters of which judicial notice may be taken." Opinion at 5-6. "If a

document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control, and the court need not accept the allegations in the complaint as true." *E.g.*, *Cont'l Bldg. Prods. Operating Co. v. Lafarge N. Am., Inc.*, No. 17-cv-2599, 2018 WL 1583309, at *4-5 (S.D.N.Y. Mar. 27, 2018) (quoting *ACE Sec. Corp. Home Equity Loan Tr. v. DB Structured Prods.*, 5 F. Supp. 3d 543, 551 (S.D.N.Y. 2014) (quoting *TufAmerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013))); *Poindexter v. EMI Record Grp. Inc.*, No. 11-cv-559, 2012 WL 1027639, at *2-3 (S.D.N.Y. Mar. 27, 2012).

ARGUMENT

Plaintiffs again fail to plausibly allege profit. Opinion at 11-15; *S. & S. Realty Corp. v. Kleer-Vu Indus., Inc.*, 575 F.2d 1040, 1044 (2d Cir. 1978). The cash consideration for Roivant's Transaction Agreement Shares was determined at the time of entry into the MOU (September 2019) and formalized in the Transaction Agreement (October 2019). TAC ¶¶ 23, 25. Roivant committed at the time of the Transaction Agreement to later purchase the Top-Up Shares and transfer them (or their voting rights) to Sumitomo at the closing of the transaction in December 2019. *Id.* ¶¶ 34-36. But, as this court explained in dismissing the SAC, "[t]he prevailing market prices of Myovant stock at the time of both the MOU and the execution of the Transaction Agreement ($7.51 and $5.46, respectively) was significantly below the prices that Roivant paid for the Top-Up Shares ($11.80 and above). Opinion at 13-14; *see also* TAC ¶¶ 50, 102.

Just as in the SAC, Plaintiffs attempt to close the gap between the $5.46 market price of Myovant shares at the time of the Transaction Agreement and the $11.80 price Roivant paid for those shares. Plaintiffs again allege that (1) Sumitomo paid Roivant a control premium for its shares above and beyond the market price; and (2) Sumitomo agreed to pay a premium because Sumitomo had access to pre-publication data from Myovant's relugolix clinical trial indicating that the drug was going to be a success. TAC ¶¶ 51-52, 116. Because the "control premium"

that Plaintiffs allege Sumitomo paid is 15%, however, that premium alone is insufficient to make up the different between the $5.46 price for Myovant shares at the time of the Transaction Agreement (or $7.51 price at the time of the MOU) and the $11.80 minimum price that Roivant paid for the Top-Up Shares. *Id.* ¶ 119. Even crediting that (generous) control premium in full, it would mean Sumitomo paid $8.64 for the Myovant shares—far less than $11.80.

Plaintiffs' claim thus rises and falls on whether Sumitomo received early information about the relugolix clinical trial. But this "sneak peek" theory is no more plausible now than it was when this court rejected it in connection with the SAC. Instead, Plaintiffs now incorporate and rely on documents that directly contradict their theory. And Plaintiffs' own allegations regarding Roivant's conduct further render implausible the inference that Roivant knew the results of the relugolix trial before the signing of the MOU.

Moreover, although the Court ruled to the contrary in dismissing Plaintiffs' complaint, Roivant respectfully suggests that Plaintiffs' allegations affirmatively show that Myovant did not incur a concrete injury in fact.

I. PLAINTIFFS STILL DO NOT PLAUSIBLY ALLEGE PROFIT.

Plaintiffs' theory of profit depends on both (a) results from the relugolix clinical study being available for use prior to the MOU's being signed in September 2019, and (b) Roivant having access to those results and sharing the information with Sumitomo. The documents Plaintiffs rely upon and their own allegations render both prerequisites implausible.

A. Plaintiffs Do Not Plausibly Allege That The Relugolix Study Data Was Available to Anyone Before the MOU Was Signed in September 2019.

Because the relugolix clinical trial was still ongoing at the time the MOU was signed in September 2019, a linchpin of Plaintiffs' sneak-peek theory is that Myovant or Roivant was able to see the results of Myovant's clinical trial before the trial had been completed. TAC ¶¶ 64-85.

To that end, Plaintiffs discuss the timeline of the relugolix trial in their complaint, drawing from the Shore Article, the NIH Summary, and excerpts of the Clinical Trial Protocol that Myovant submitted to the FDA. *Id.*; *see, e.g.*, *id.* ¶ 70 ("To understand how Roivant could know the outcome while the trial was still ongoing, some discussion of the trial protocol is necessary."); NIH Summary (TAC Ex. G); Excerpts of Clinical Trial Protocol (TAC Ex. I); Shore Article (TAC Ex. J).

These documents—especially the full Clinical Trial Protocol attached as an exhibit to this motion—contradict Plaintiffs' sneak-peek theory and show that no one had access to the data before the MOU was signed.

First, Plaintiffs do not plausibly allege that anyone at Myovant or Roivant was able to infer the potential efficacy of relugolix during the clinical trial. Plaintiffs rely on the fact that the study was "open-label," meaning that physicians and patients knew which drug a patient had received. *See* TAC ¶ 75; Excerpts of Clinical Trial Protocol (TAC Ex. I) at 55 ("Blinding is not applicable; this is a randomized open-label study."); Shore Article (TAC Ex. J) at 2188 ("The HERO trial is a multinational, randomized, open-label, phase 3 trial."). But that is not all Plaintiffs' cited documents have to say on blinding. The trial depended on measuring patients' testosterone levels. *E.g.*, TAC ¶¶ 71-73. Doctors do not measure testosterone levels themselves; samples from the patients were periodically sent to a central laboratory where their testosterone levels were measured. Clinical Trial Protocol (Williams Decl. Ex. 1) at 168-69; Shore Article (TAC Ex. J) at 2188. The data reviewed by this central laboratory *was blinded.* As the Shore Article states: "Testosterone values for the primary end-point analysis were measured at a *blinded* central laboratory." Shore Article (TAC Ex. J) at 2188 (emphasis added).

That means that the laboratory measuring testosterone levels did not know whether a patient had received relugolix or the control medication, leuprolide. Plaintiffs have alleged no

facts to support a plausible inference that Myovant (let alone Roivant) for some reason unblinded the data at the central laboratory *in the middle of the clinical trial* to get an early peek at the efficacy results. Common sense suggests Myovant would not undermine its clinical trial by interfering with its blinding, which is "a critical determinant of [the] quality and persuasiveness" of its trial. FDA, *Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials* (May 2001), *available at* https://www.fda.gov/media/71349/download, at 3; *Abely v. Aeterna Zentaris Inc.*, No. 12-cv-4711, 2013 WL 2399869, at *7 (S.D.N.Y. May 29, 2013) (taking judicial notice of the discussion of blinding in this document). Plaintiffs plead no facts to explain how Myovant or Roivant received early knowledge of the clinical trial results from this blinded laboratory.

Second, even setting aside the blinding issue, the Clinical Trial Protocol contradicts Plaintiffs' allegations that anyone had analyzed the efficacy of relugolix before the end of the clinical trial. Plaintiffs suggest that the protocol envisioned rolling measurement and analysis of patient data. *See, e.g.*, TAC ¶¶ 73-77. But the Clinical Trial Protocol lays out an entirely different process. As the protocol explains, the "primary analysis" of the safety and efficacy of relugolix would occur *after* 915 patients "had the opportunity to be evaluated for 48 weeks *and* complete the 30-day safety follow-up visit." Clinical Trial Protocol (Williams Decl. Ex. 1) at 121 (emphasis added). That approach is consistent with the "primary clinical outcome to be measured"—in the language of the study, the "primary endpoint"—which was sustained testosterone suppression for 48 weeks. TAC ¶ 71.

The primary analysis was also the first analysis. The Clinical Trial Protocol explains that there was no "interim efficacy analysis" before the primary analysis. Clinical Trial Protocol (Williams Decl. Ex. 1) at 186. Even though several "secondary endpoints" (i.e., secondary measures of the safety or efficacy of relugolix) relied on data "measured in the first few weeks of

treatment," TAC ¶ 79, the protocol states that secondary endpoints would be analyzed only *after* the primary analysis yielded positive results. *See* Clinical Trial Protocol (Williams Decl. Ex. 1) at 183 ("If the result of the primary endpoint is statistically significant, the secondary endpoints will be analyzed.").

Critically, the Clinical Trial Protocol shows that the primary analysis did not begin until November 2019—after the MOU and Transaction Agreement had been signed. The Clinical Trial Protocol states that the "primary analysis" would not occur until after the statistical analysis plan had been "*prepared and finalized*." *Id.* at 121 (emphasis added). When the MOU was signed, there was no statistical analysis plan in effect. The first plan was approved by Myovant a week after the MOU was signed, on September 12, 2019. *Id.* at 321. Myovant continued to refine the statistical analysis plan in light of FDA comments, and approved a final version on November 7, 2019. *Id.* at 379, 436. Plaintiffs allege no facts supporting an inference that Myovant deviated from what it told the FDA in the Clinical Trial Protocol, and somehow began analyzing the efficacy of relugolix before finalizing its methodology for doing so. To the contrary, Plaintiffs rely on the accuracy of the Clinical Trial Protocol in making their allegations about the relugolix trial. *E.g.*, TAC ¶¶ 70, 72.

The timeline from the documents attached to Plaintiffs' complaint is therefore as follows:

- April 2017 – Clinical Trial Enrollment Begins
- Oct. 2018 – Sufficient Patients Enrolled in the Trial
- *Sept. 6, 2019 – Memorandum of Understanding Signed – Consideration Set*
- Sept. 12, 2019 – Date of First Statistical Analysis Plan Draft
- Oct. 25, 2019 – Last Patient's Samples Collected for Analysis

- *Oct. 31, 2019 – Transaction Agreement Signed*
- Nov. 7, 2019 – Final Version of Statistical Analysis Plan Approved
- Nov. 7-19, 2019 – Primary Efficacy Analysis Performed
- Nov. 19, 2019 – Clinical Trial Results Announced
- Nov. 20 - Dec. 17, 2019 – Roivant Purchases Top-Up Shares
- *Dec. 27, 2019 – Transaction Closes*

Here, "the documents attached to" and incorporated in the TAC "contradict the allegations." *Cont'l Bldg. Prods. Operating Co.*, 2018 WL 1583309, at *5; *see Blue Tree Hotels Inv. v. Starwood Hotels & Resorts Worldwide Inc.*, 369 F.3d 212, 222 (2d Cir. 2004) (rejecting inference when attached documents "belied" allegations); *Poindexter*, 2012 WL 1027639, at *1-3 (dismissing complaint where allegations were "inconsistent" with agreement attached to complaint); *Rapoport v. Asia Elecs. Holding Co.*, 88 F. Supp. 2d 179, 183-87 (S.D.N.Y. 2000) (dismissing complaint where "the two documents upon which Plaintiffs rel[ied] . . . . contradict[ed] Plaintiffs' allegations"). Plaintiffs certainly lack a "*reasonable* inference" that anyone (i.e., Myovant or Roivant) had knowledge of the relugolix trial results before the MOU or the Transaction Agreement was signed. *Pension Benefit Guar. Corp.*, 712 F.3d at 718–19 (citing *Iqbal*, 556 U.S. at 678).

B. Plaintiffs Do Not Plausibly Allege that Roivant In Particular Had Early Knowledge of the Relugolix Clinical Trial Results.

The above analysis shows that it is implausible that *anyone*, much less Roivant, had early access to the results of the relugolix study. But Plaintiffs' claim would be implausible even if Myovant knew the results early, because their theory depends on *Roivant* knowing and *Roivant* sharing the information with Sumitomo. *See* TAC ¶¶ 56-59, 65-70. Plaintiffs allege two theories as to how Roivant had access, but both are implausible for reasons beyond the analysis above: One is that Roivant had access to the data "through its representatives on Myovant's board." *Id.*

¶ 56. The other, on which Plaintiffs focus, is that "the study was actually overseen by Roivant." *Id.* ¶ 65; *see id.* ¶¶ 66-70. Both theories are fatally flawed.

First, Plaintiffs' allegations that Roivant ran the clinical trial are again contradicted by the documents on which they rely. Plaintiffs concede that the trial was "formally sponsored by Myovant Sciences GmbH." *Id.* ¶ 65. The documents Plaintiffs attach confirm Myovant's role overseeing the study, listing Myovant as the "Sponsor" and the "Responsible Party." NIH Summary (TAC Ex. G) at 1. The NIH Summary further confirms that the investigators for the study were affiliated with Myovant, *not Roivant*. *Id.* at 10. The Clinical Trial Protocol is to the same effect, and indeed states that the confidential information in the protocol was "the property or under control of Myovant Sciences GmbH." Excerpts of Clinical Trial Protocol (TAC Ex. I) at 1. Every single page of the protocol lists "Myovant Sciences GmbH" in the footer. *See generally id.*; Clinical Trial Protocol (Williams Decl. Ex. 1). The Shore Article, also attached to the TAC, further confirms that Myovant "[f]unded" the study, was the study's "sponsor," designed the trial with the steering committee, and eventually reviewed the data with the steering committee and study authors. Shore Article (TAC Ex. J) at 2187-88. None of the authors of the Shore Article or any of the relugolix study investigators listed in the supplemental appendix to the article disclosed any affiliation with Roivant. *Id.*; NEJM Supplementary Appendix (Williams Decl. Ex. 3). In fact, our review indicates that the word "Roivant" does not appear anywhere in the NIH Summary, the Clinical Trial Protocol, or the Shore Article.

Plaintiffs' entire basis for claiming that Roivant was truly in charge is a November 11, 2016 Amended & Restated Services Agreement (the "Services Agreement") between a Roivant subsidiary Roivant Sciences, Inc. ("RSI") and Myovant, pursuant to which Myovant had the right to engage RSI to provide certain services, including those related to management of clinical testing. TAC ¶¶ 66-67; *see* Services Agreement (TAC Ex. H) at 3 (retaining RSI "to perform the

services [Myovant] *requires* from among those set forth" on the list of services to which Plaintiffs cite) (emphasis added). But a service contract, pursuant to which Myovant *could* request certain services from RSI, does not mean that Myovant *did* request them. Roivant's complete absence from the documents about the study confirms that Roivant did not oversee the trial.

Given the terms of the Services Agreement, Roivant's absence from the documents is not surprising. The Seventh Recital establishes that Myovant desired to engage RSI "*until such time as [Myovant] is able to provide all of the services* required." Services Agreement (TAC Ex. H) at 2 (emphasis added).[2] Plaintiffs allege no facts to suggest why Myovant, as the sponsor of the relugolix study, did not oversee the study itself and needed Roivant's assistance under the agreement. To the contrary, Plaintiffs incorporate documents that show Roivant was not involved.

Second, even if Myovant had provided Roivant with confidential information about the relugolix clinical trial, Roivant could not use or disclose that information to any other entity—like Sumitomo. That follows from the Services Agreement, which protects confidential information shared between Roivant and Myovant, however it is shared. Services Agreement (TAC Ex. H) ¶ 6.1. Any partial set of clinical results months before their public release—which, to be clear, did not exist—would surely qualify for such protections. Either they would have been expressly designated as confidential or "understood by a reasonable person to be proprietary and nonpublic." *Id.* As such, any Roivant employees or executives who would have

[2] Technically, the Services Agreement involves multiple, related Myovant entities; and it accordingly contemplates that "services [are] required" by one Myovant entity and provided by another. *See id.*

learned the information would be required to keep the information "in confidence" and to "refrain from using or exploiting any and all" of what they learned. *Id.* ¶¶ 6.1, 6.3. Plaintiffs have no allegations that Roivant executives violated their obligations to Myovant.

Third, and most significantly, Plaintiffs have affirmatively alleged that Roivant did not misuse any confidential clinical data. Plaintiffs rightly recognize that they are claiming Roivant had "material" information about Myovant, and they affirmatively allege that Roivant adhered to its obligations to "disclose or abstain" from trading in Myovant stock accordingly. *See, e.g.*, TAC ¶¶ 86-87. In fact, they claim that the Court should infer from Roivant's lack of trading in Myovant stock after the Transaction Agreement was signed that Roivant had known about the result of the clinical trial all along. *Id.* ¶ 53.[3] But Plaintiffs have also alleged that Roivant purchased over 2.4 million shares of Myovant stock in June 2019 at $8.25 per share. *Chechele* Compl. ¶ 20(a); *see* Form 4 (Williams Decl. Ex. 4).[4]

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[3] Otherwise, Plaintiffs would be alleging that Roivant engaged in insider trading, and their complaint would be subject to Rule 9(b). *See, e.g.*, *Applied Energetics, Inc. v. Stein Riso Mantel McDonough, LLP*, No. 19-cv-1232, 2020 WL 2833686, at *5 (S.D.N.Y. May 31, 2020) (noting insider-trading allegations are subject to Rule 9(b); *see generally, e.g.*, *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 183 (2d Cir. 2014) (noting that Rule 9(b) applies to claims premised on fraud).

[4] The Form 4 showing Roivant's June 2019 purchase was relied on in preparing the *Chechele* complaint and Plaintiffs knew of the transaction when putting together their complaint. The Form 4 can therefore be considered in connection with this motion. *See* Opinion at 5-6; *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991) (district court properly considered several

Plaintiffs' theory is that Roivant knew the relugolix study would be a success far before June 2019. Their claim, after all, is that Roivant learned the "jackpot evidence" of relugolix's superiority on a rolling basis, beginning during the "earliest weeks of treatment," which they allege occurred in 2017-18. TAC ¶¶ 80, 82; *see id.* ¶¶ 76-85. Those allegations are contradicted by Roivant's having traded in Myovant stock in June 2019 (purchasing stock at a price Plaintiffs allege was drastically undervalued)—especially given Plaintiffs' affirmative allegations that Roivant did not engage in insider trading. TAC ¶¶ 53, 82-83.

* * * *

For the foregoing reasons, Plaintiffs' sneak-peek theory is contradicted by the documents on which they have constructed it. The Clinical Trial Protocol shows that there was no usable data from the clinical trial until November 2019—after both the MOU and the Transaction Agreement were signed. That is alone sufficient to defeat Plaintiffs' claim. But their allegations separately show that Roivant in particular did not have access to the clinical data. Plaintiffs' documents show that Roivant did not run the clinical trial and could not use any information that it learned about the trial. In fact, Plaintiffs have affirmatively alleged that Roivant did not trade on Myovant's confidential information, and thus could not have had such information when it bought millions of shares of Myovant stock in June 2019.

II. THE COURT SHOULD RECONSIDER ROIVANT'S OTHER GROUNDS FOR DISMISSAL.

We recognize that the Court denied two of Roivant's grounds for dismissal in the Opinion dismissing the SAC. *See* Opinion at 6-13. Although we continue to assert that both

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SEC documents such as Form 8-K and a Joint Proxy statement in case where such documents were at issue).

arguments have merit, we are not repeating the arguments here except to respectfully submit that, under the Court's analysis regarding Article III standing, Plaintiffs have not pleaded a concrete injury on the part of Myovant.

The Court ruled that Plaintiffs had pleaded a concrete injury in fact to Myovant based on the Supreme Court's decision in *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540 (2016), and the Second Circuit's decision in *Donoghue v. Bulldog Investors General Partnership*, 696 F.3d 170 (2d Cir. 2013). Opinion at 8-11.[5] The Court reasoned that, under *Spokeo*, Section 16(b) raised a question of standing for a procedural violation. *E.g.*, Opinion at 7. Under *Bulldog*, however, the underlying right of the issuer to collect short-swing profits is "substantive." 696 F.3d at 175. (The ability of shareholders to pursue the claim for the company is a "procedural device," but not the claim itself. *Id.* (quotation marks omitted).) Accordingly, *Spokeo*'s analysis regarding when a concrete injury has been pleaded for a procedural violation should be inapplicable.

Under the procedural-violation analysis, however, we respectfully submit that a concrete injury in fact has not been shown. As applied by the Second Circuit, the *Spokeo* analysis for a procedural violation asks if "(1) 'Congress conferred the procedural right to protect a plaintiff's concrete interests as to the harm in question,' and (2) 'the procedural violation presents a risk of real harm to that concrete interest.'" Opinion at 8 (quoting *Katz v. Donna Karan Co. Store, L.L.C.*, 872 F.3d 114, 119 (2d Cir. 2017)). Section 16(b) is clear about the concrete interest it seeks to

[5] We maintain that *Bulldog* is inconsistent with *Spokeo*. Although the Second Circuit cited *Bulldog* favorably in *Klein v. Qlik Technologies, Inc.*, 906 F.3d 215, 220 (2d Cir. 2018), *Klein* did not involve a question of injury to the issuer. The question was whether the purchaser (i.e., the party situated similarly to Plaintiffs here) had lost standing as a result of a buyout. *Id.* at 220.

protect: "the unfair use of information which may have been obtained by" owners, directors, or officers. § 78p(b).

The question under the Second Circuit cases thus becomes whether the procedural violation presents a "risk of real harm" of unfair use of inside information. *E.g.*, *Katz*, 872 F.3d at 119. Here, Plaintiffs' allegations, including the documents their pleading incorporates, shows that Roivant did not have access to confidential information about Myovant. *See supra* pp. 12-20. But, even on Plaintiffs' implausible allegations, they have affirmatively alleged that Roivant did not misuse any information, but instead disclosed it to Sumitomo and did not trade in the market until Myovant disclosed its test results. *See* TAC ¶¶ 53, 82-83. Moreover, Myovant approved the Roivant-Sumitomo transaction in a public filing. *See* Myovant 8-K (Williams Decl. Ex. 2). Plaintiffs' allegations and documents appropriately considered in a challenge to standing show that Plaintiffs have not "demonstrate[d] sufficient risk of harm" for Article III purposes. *Strubel v. Comenity Bank*, 842 F.3d 181, 190 (2d Cir. 2016); *see Katz*, 872 F.3d at 119-20.

Accordingly, we respectfully ask that the Court reconsider its holding that Plaintiffs had adequately pleaded Article III standing.

CONCLUSION

For the foregoing reasons, the Court should dismiss the Third Amended Complaint with prejudice.

Dated: March 12, 2021
Washington, D.C.

Respectfully submitted,

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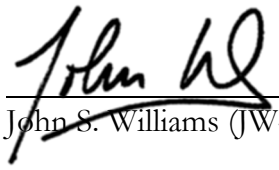
CERTIFICATE OF COMPLIANCE
WITH FORMATTING AND WORD-COUNT REQUIREMENTS

I, John Williams, counsel for Roivant Sciences Ltd. and a member of the bar of this Court, certify that the Memorandum of Law in Support of the Motion of Roivant Sciences Ltd. to Dismiss the Third Amended Complaint contains 6,912 words, and complies with the formatting requirements of Section II.D of the Individual Practices of the Hon. John G. Koeltl.

Dated: March 12, 2021
Washington, D.C.



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